

REMARKS

Claims 8-34 were rejected under §112, first paragraph and have been amended to provide that both ends of the blood filter and spacer layers are sealed. Reconsideration and withdrawal of the rejection are respectfully requested.

Art was not applied against claims 11, 13, 18-19, 21-22, 24-26 and 31-32 and it is presumed that these claims include allowable subject matter.

Claims 8-10, 14-15, 27-29 and 33-34 were rejected as anticipated by LOFT 4,028,250. Claims 16-17 and 23 were rejected as anticipated by HOPKINS 5,266,195. The claims have been amended and reconsideration and withdrawal of the rejections are respectfully requested.

The amended claims are directed to embodiments of the present invention that include a coiled core with a hollow center. The core has only two layers that are coiled atop one another, the two layers being a blood filter layer and a spacer layer where blood flows more easily through the spacer layer than through the filter layer. Both ends of the blood filter and spacer layers are sealed. The blood filter layer comprises a nonwoven fabric made of fibers having a mean diameter of not less than 0.3  $\mu\text{m}$  and less than 5.0  $\mu\text{m}$  (support for this feature is found at page 6, lines 3-5, and the term "nonwoven fabric" is defined on page 5, beginning at line 21.) An outer side of one

of the spacer layer and the filter layer defines an outer circumference of the core. The filter and spacer layers are coiled so that both sides of the filter layer directly contact respective sides of the spacer layer. A casing for the core has a blood inlet in fluid communication with the outer circumference of the core and a blood outlet in fluid communication with the hollow center. Blood entering the inlet travels to the outlet within the spacer layer and transversely across the filter and spacer layers.

LOFT relates to a filtration apparatus for removing particles from a liquid suspension. LOFT further describes a filtering member composed of two sheets of microporous filter materials and a mesh-like spacing material that are superimposed relative to each other and spirally wound. As the microporous filter material, a filter material comprises a polymeric resinous matrix with inorganic filler particles and micropores formed between adjacent particles of the dispersed filler as well as semi-rigid sheet fabricated therefrom (column 4, lines 10-36). The apparatus of LOFT is useful as a preultrafilter in a desalinization system employing reverse osmosis (column 1, lines 10-12). LOFT also mentions that ultrafiltration has also been employed recently in the fractionation of blood (column 2, lines 22-23).

HOPKINS relates to a semi-permeable filter apparatus having a membrane spirally wound. HOPKINS describes a sandwich-like sheet formed from a spirally wound semi-permeable membrane and a spacer. As semi-permeable membranes, reverse osmosis or ultrafiltration membranes are mentioned (column 3, lines 64-68). Sheet materials may be suitable ones such as are well known in the art, including porous fabric material, a felt, knitted or woven materials and further RO membranes or UF membranes (column 4, lines 36-54). According to HOPKINS, greater amounts of active membrane surface area per unit volume can be achieved by optimizing the spirally wound membrane element designs (column 2, lines 33-39).

In contrast, the filter device claimed herein has, as a filtering element, a non-woven fabric made of fibers having the mean diameter of not less than 0.3  $\mu\text{m}$  and less than 5.0  $\mu\text{m}$ . The filter device has excellent blood fluidity and leukocyte removal from a body fluid such as blood. Further, the filter device can prevent the local and acute activation of blood coagulation components since the specific spirally wound structure, particularly the specific location of the spacer, causes the flow of blood transverse to the filter layer as well as the flow of blood toward the inner circumferential surface of the filter along with the spacer. As a result, substances to be removed, primarily leukocytes, can be highly efficiently removed from a

large amount of blood without reducing the filtration rate and, while suppressing the increase of pressure.

None of the above-mentioned references describes removing leukocytes from blood using the particularly claimed non-woven filter. None of the above-mentioned references describes forming a particularly spirally wound structure composed of the non-woven filter and spacer, whereby the local biased flow during the filtration of blood is prevented to inhibit blood coagulation and eventually suppress the increase of pressure. Accordingly the amended claims are believed to be patentable.

Claims 12, 20 and 30 were rejected as unpatentable over LOFT in view of VAN WIJK 4,872,990.

VAN WIJK relates to a membrane module for reverse osmosis or ultrafiltration having a membrane envelope for retaining and permeating a liquid flow which is spirally wound around a tube. The object of VAN WIJK is to provide a membrane module which has a favorable ratio between membranes surface area and module volume, which has a very constant and defined geometry of the retentate flow channels and which is not susceptible to blockage (column 1, lines 6-63). In VAN WIJK, a spacer is interposed between a membrane spirally wound. The diameter of this spacer is limited to 0.5 to 2.5 mm, which is supposed to be less likely to cause blockage (column 1, line 64 to column 2,

line 11). Blood plasma is mentioned as an example of liquids to be treated (column 3, line 21). In the membrane module of VAN WIJK, as a consequence of the construction of the retentate spacer in the form of rods, a good flow parallel to the rods direction along the membrane surfaces can be obtained with very little risk of blockage (column 4, lines 18-27).

In contrast, the filter device of the present invention has, as the filtering element, a non woven fabric made of fibers having the mean diameter of not less than 0.3  $\mu\text{m}$  and less than 5.0  $\mu\text{m}$ . The filter material formed from this filtering element and a spacer that are wound in a specific manner is accommodated by a casing, whereby leukocytes can be removed from the blood and the local and acute blood coagulation due to the convergence of blood to a narrow region can be prevented.

VAN WIJK describes a filter composed of reverse osmosis membranes or ultrafiltration membranes and does not describe removing particular blood components, particularly leukocytes, with a non-woven filter. VAN WIJK mentions flowing plasma but does not mention flowing it without causing the coagulation of blood. Since blood contains platelets as well as plasma proteins, it is more likely to be coagulated than plasma. Since the filter device of the present invention can alleviate the local convergence of blood by dispersing the flow of blood both in the inner circumferential direction and in the outer

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circumferential direction, the blockage due to the coagulation of blood can be prevented. VAN WIJK does not describe or suggest such an effect of the present invention.

None of the cited references discloses the claimed non-woven fabric filter, removal of leukocytes, blood treatment, prevention of blood coagulation and prevention of blockage of the filter. Thus, the present invention should not be rendered obvious over these references.

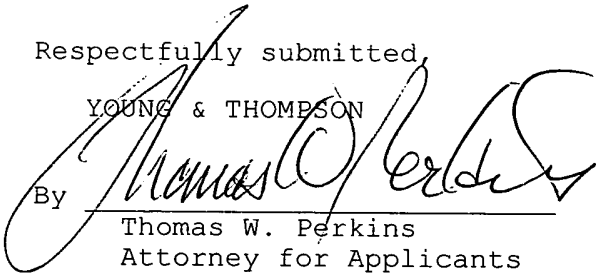
In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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